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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/216,609	12/21/1998	HANS JOHN HANSEN	018733/0734	9388
7590 03/08/2004				
FOLEY & LARDNER 3000 K STREET SUITE 500 WASHINGTON, DC 200075109			EXAMINER YAEN, CHRISTOPHER H	
			ART UNIT 1642	PAPER NUMBER

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/216,609

Applicant(s)

HANSEN, HANS JOHN

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-26, 29 and 30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-26, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: wed pages--Merriam-Webster definitions.

DETAILED ACTION

1. The amendment filed 10/20/2003 is acknowledged and entered into the record.
2. Claims 23-26 and 29-30 are pending and examined on the merits.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections Maintained - 35 USC § 102

4. The rejection of claims 23-26 under 35 USC 102(b) as being anticipated by Bagshawe *et al* is maintained for the reasons of record. Applicant argues that the difference between the instant invention and that of Bagshawe *et al* is in the number of components used in the system, wherein the instant invention consists of five components and that of the prior art consists of three components. Applicant's arguments are not deemed persuasive because the claims of the instant invention recite "optional" steps. These steps are read to the extent that they may or may not be required steps. The common definition of the term *optional* is "involving an option", wherein an *option* is "the power or right to choose" (as evidenced Merriam-Webster Online--attached). Because steps (b) and (d) are not required steps, the invention therefore involves a three component system wherein there is a multispecific targeting protein (which has the binding specificity of a target protein and an enzyme), an enzyme, and a prodrug. Bagshawe *et al* discloses a bivalent targeting protein (wherein there is specificity for a tumor marker and a specificity for an enzyme) an enzyme and then a prodrug (see page 5 lines 17-25 and page 6 lines 1-2). Therefore the system is of the instant invention is identical to that of Bagshawe *et al*.

Furthermore, applicant argues that basic mechanism of the therapy is also different wherein the method of the prior art uses an enzyme to activate a substrate already localized to a specific target, while that of the instant invention uses an enzyme-substrate complex that later activates a prodrug (see arguments filed on 10/20/2003). Applicant's arguments have been carefully considered but are not found persuasive because the method claimed appears to be same as that disclosed by Bagshawe *et al.* It is disclosed in the prior art that a targeting molecule is first administered, followed by an enzyme and lastly by a prodrug (see page 3 lines 1-15 and page 5 lines 17-25). The targeting molecule, as stated above can be a bivalent molecule as disclosed on page 5 lines 17-25, which is followed by the administration of an enzyme which later activates a prodrug. All the limitation of the recited method are anticipated. Thus applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections Maintained - 35 USC § 103

5. The rejection of claims 23-26 and 29-30 under 35 USC 103(a) as being obvious over Bagshawe *et al* in view of Tsuji *et al* and Houba *et al* is maintained for the reasons of record. Applicant argues that Bagshawe *et al* fails to disclose the five component system for the instant invention, but rather teaches a three component system. This argument has been considered but is not persuasive for the reasons set forth above.

Applicants additionally argue that the combination of Bagshawe *et al* in view of both Tsuji *et al* and Houba *et al* do not cure the deficiencies of the Bagshawe *et al* reference. Applicant's arguments have been considered but are not persuasive because one of skill in the art would have found motivation in using the enzymes and

the prodrug taught by both Tsuji *et al* and Houba *et al* because both items have been taught as representative components for use in ADEPT. The motivation in using such enzymes rests in the fact that both esterases and glucuronidase are responsible for the activation of specific prodrugs such as CPT-11. There is a high expectation of success in combining the references because the enzymes and prodrug taught by Tsuji *et al* and Houba *et al* have already been shown to be effective and functional in ADEPT. Thus applicant's arguments have not been found persuasive and the rejection is maintained.

Conclusion

6. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

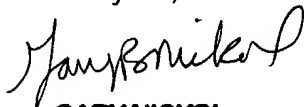
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
February 24, 2004


GARY NICKOL
PRIMARY EXAMINER